

REMARKS

Reconsideration and reexamination of this application are respectfully requested.

The listing of claims amends claims 15 and 23, and cancels claim 19. The amendments find support throughout the application and do not introduce new matter. Claims 15-18 and 20-26 are pending and stand rejected.

A. The nonstatutory double-patenting rejection.

Claims 15-16 stand provisionally rejected for nonstatutory double patenting over claims 1-8 and 15-26 of Application No. 10/595,045. Applicant respectfully requests that that rejection be held in abeyance until claims in one of the applications are allowed.

B. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 15 stands rejected as allegedly indefinite for reciting “providing the ratio for a user.” Applicant respectfully points out that that phrase does not appear in the claims. Applicant is accordingly unsure of the basis for the rejection. Applicant requests that the Examiner contact the undersigned regarding any concerns the Examiner has regarding the definiteness of the claims that are not addressed herein.

Claim 25 stands rejected as allegedly indefinite for the recitation “the on-target effect distance” in line 2. The basis for this rejection is the Examiner’s concern that claim 23, from which claim 25 depends, recites “target effect distance.” Applicant has followed the Examiner’s suggestion and amended claim 23 to recite “an on-target effect

distance." Applicant thanks the Examiner for the suggestion and submits that the rejection should be withdrawn.

C. The Rejection Under 35 U.S.C. § 103(a)

Claims 15-26 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Johnson (U.S. Patent No. 6,611,833) in view of Friend (US Patent No. 6,801,856). (Office Action at pages 4-10.)

Applicant respectfully traverses the rejection. During Examination: "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." M.P.E.P. § 2142. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2142. Applicant will show that the Office has not met *any* of the required elements to make out a case of *prime facie* obviousness.

Amended claim 15, and claims 16-18 and 20-26 as they depend from claim 15, recite "A method of characterising a treatment applied to a population of cells, comprising: providing a treatment to a population of cells; [and] deriving a plurality of

cellular features from at least a first captured image of the population of cells that have been exposed to the treatment.” The plurality of cellular features derived from that treated cell population is then used in further steps in the claims. An “on-target effect signature [is created], which is characteristic of an on-target effect of the treatment on the population of cells, from at least a first one of the plurality of cellular features derived from the population of cells, the at least one of the plurality of features relating to cellular properties involved in the on-target effect.” A “side effect signature [is also created], which is characteristic of a side effect to the on-target effect, from at least a second one of the plurality of cellular features derived from the population of cells, the second one of the plurality of cellular features relating to cellular properties not being involved in the on-target effect.” The language of amended claim 15 makes clear that the on-target effect signature and the side effect signature are both created from the plurality of cellular features that are derived from the population of cells that is treated. Thus, both signatures are created from a single treated population of cells.¹

That method of creating both an on-target effect signature and side effect signature from the cellular features of a single, treated population of cells, then allows for “creating an on-target effect metric derived from the on-target effect signature; creating a side effect metric derived from the side effect signature; and comparing the on-target effect metric to the side effect metric to thereby characterise the response of the population of cells to the treatment.”

¹ Applicant has also canceled claim 19, which may have created ambiguity as to this aspect of claim 15.

In the Office Action the Examiner repeatedly states that Johnson teaches creating an on-target metric and side effect metric by looking at normal and abnormal tissues. However, those methods of Johnson are clearly not the same as the claimed methods of creating on-target and side effect metrics of the *same* tissue, when that tissue is treated.

Friend describes creating a consensus response profile for a tissue, then creating a biological response profile of a tissue following a treatment, and finally comparing the two in order to characterize the treatment. Essentially, what Friend describes is a method of measuring one characteristic of a tissue following a treatment and then comparing the measurement to a previously determined characteristic of a known tissue. Such a method is different than a method of creating an on-target effect signature and a side effect signature both from a plurality of cellular features that are derived from a single population of cells that is treated, as in the amended claims.

The Examiner has not pointed to any suggestion or motivation in the art to modify the prior art teachings to arrive at the claimed invention. Instead, the Examiner states that a passing reference of Johnson to the use of the methods disclosed therein in drug design would lead the skilled artisan to the claimed invention. Applicant respectfully disagrees.

It is possible that the methods of either Johnson or Friend could be used in drug design in some way. For example, to compare the effect of a drug treatment on a tissue to the condition of a normal tissue or an abnormal tissue that is not treated with that drug, or to tissues treated with other drugs. However, the references do not teach or

fairly suggest modifying the disclosed methods to arrive at a method of creating an on-target effect signature and a side effect signature both from a plurality of cellular features that are derived from a single population of cells that is treated, as in the amended claims.

Because the Office has not identified any such teaching or suggestion the Office has failed to carry its burden of making out a *prima facie* case that the claims are obvious. Accordingly, Applicant respectfully submits that the obviousness rejection should be withdrawn.

D. Conclusion

Applicant respectfully submits that claims 15-18 and 20-26 are patentable.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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